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HOWREY SIMON ARNOLD & WHITE

JUN - 7 2000



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WASHINGTON, D.C.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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03/844,236 04/18/97 CONTAG

P 8678-004-999
7953-0004-999

022930 HM12/0605
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EXAMINER

RYAN, V

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

06/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

book
PATTSY

9400-0005
DOCKETED
ROA 9/5/00
LD 12/5/00

DOCKETED adc 6.7.00
Response Due 9.5.00
Last Day 12.5.00

FMP

Office Action Summary

Application No.
08/844,336

Applicant(s)
Contag et al

Examiner
V. Ryan

Group Art Unit
1641

☒ Responsive to communication(s) filed on Jan 3, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) 10-20 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 and 21-27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

✓ ☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1641

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges receipt of the amendment, substitute specification, and oath/declaration filed January 3, 2000.

In this application:

Claims 1 and 21 were amended.

Claims 1-27 are pending.

Claims 10-20 are withdrawn by the Examiner as being drawn to a nonelected invention.

Claims 1-9 and 21-27 are now under examination.

Response to Amendment

The substitute specification and oath/declaration filed January 3, 2000 has been entered.

The corrected or substitute drawings were received on January 3, 2000. These drawings are approved by the draftsman.

Art Unit: 1641

(1) The rejection of claims 1-9 and 21-27 under 35 U.S.C. 112, first paragraph is withdrawn.

(2) The rejection of claims 21, 22, 25 and 26 under 35 U.S.C. 112, first paragraph for containing subject matter which was not described in the specification is maintained in part.

Applicant asserts that the specification provides support for a biodetector which is "sheltered in a genetically engineered bacterial cell."

While the specification (page 13, lines 28-29) teaches examples of living cells which can be genetically altered for use as biodetectors. The specification does not appear to teach a biodetector within a genetically engineered cell.

(3) The rejection of claims 1-9 and 21-27 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment to the claim.

(4) The rejection of claims 1-9 and 22-24 under 35 U.S.C. 103 as being obvious by Karube et al and Sleight et al is withdrawn. A modified rejection is set forth below.

(5) The rejection of claims 21 and 25 under 35 U.S.C. 103 as being unpatentable by karube et al and Sleight et al (as applied

Art Unit: 1641

to claims 1-9 and 22-24) and further in view of Miller et al is withdra

The following are new grounds of rejection:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 21-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 09/183,566. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both application are directed to the biodeceptor comprised of a signal converting element, a transducer, and a responsive element. The claims of Application 09/183566 additionally include the limitation of "a reporter gene

Art Unit: 1641

operatively linked to said responsive element, wherein the activated responsive element causes expression of the reporter gene to generate a reporter gene product, resulting in a detectable signal." While this limitation is not specifically recited in claim 1 of Application No 08/844,336, the claim indicates a detectable signal is produced.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

Art Unit: 1641

art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 22-23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Karube et al in light of Sleight et al.

Karube et al anticipates claims 1-9, 22-24 and 27. Sleight et al is not used as a secondary reference in combination with Karube et al, but rather is used to show that every element of the claimed subject matter is disclosed by Karube et al because Sleight et al teaches the signal transduction pathways that are known to exist in all living cells. That is, the reference teaches signal transduction pathways whereby an extracellular signal molecule binds to a native receptor on the cell surface, which then results in the generation of an intracellular signal. (See *In re Samour* 197 USPQ 1. (CCPA 1978)).

Karube et al teach biosensor cells used for the detection and analysis of specific substrates. The biosensors are

Art Unit: 1641

comprised of a microorganism sensing element which recognizes specific substrates, and a transducer to convert the biochemical signal produced into an electronic signal. (See especially page 54, first column).

Karube et al teach that the transducer can be a photo detector, potentiometric electrodes, amperometric electrodes and thermistors. (See especially page 54, second column).

The reference also discloses that the visible reaction observed can be luminescence by fusing the luxAB gene to the fixAB gene. (See especially page 56, first column).

Karube disclose biosensors, however, the reference does not specifically recite the extracellular ligand-specific moiety and an intracellular signal transforming domain.

Sleight et al teach that a variety of substances act as extracellular signals by binding to specific receptors located on the cell surface. By a process known as signal transduction, the extracellular signal stimulates an intracellular change which leads to the formation or release of an intracellular signal. (See especially page 117).

Therefore, without evidence to the contrary, the biosensor taught by Karube et al would appear to be the same as that recited in the claims.

Art Unit: 1641

Claims 21 and 25 are rejected under 35 U.S.C. 103 as being obvious by Karube et al in light of Sleight et al (as applied to claims 1-9, 22-23 and 27) and further in view of Garcia Vescovi et al.

The teachings of Karube et al in light of Sleight et al were set forth above. The references, however, differ in not teaching to PhoQ 2-component regulatory system as the signal transducer.

Garcia Vescovi et al (Cell 84:165-174, 1996) teaches the use of PhoQ as a signal transducer in response to the extracellular signal produced by magnesium cations. PhoP and phoQ are the regulatory and sensory proteins of the two-component system known as PhoP/PhoQ. Bacterial cells are able to modulate transcription of genes in response to the level of magnesium in the environment.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bioreactor of Karube et al with the signal transduction system of Garcia Vescovi et al. One of ordinary skill in the art would have been motivated to do this in order to detect the presence or absence of magnesium in an environment.

Art Unit: 1641

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1641.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
May 2000
Ryan/vr


JAMES C. HOUSEL 5/22/00
PATENT EXAMINER